

that the unique and patentable aspects of the subject matter of both inventor's earlier invention of the '506 patent and that of the present application are characterized as methods, not apparatus. When the claimed method and steps for carrying out are considered in contrast to the method and steps of the '506 patent, it will be fully appreciated that the method of the present application is clearly patentable over the disclosure of the '506 patent.

As noted in the introductory portions of the present application, while the gas exchange function of the lungs may be uniform throughout the pulmonary volume for healthy lungs, this may not be the case for diseased lungs. In the latter, gas exchange may not be homogenous in the lungs.

The present invention provides a method by which data for determining the degree of homogeneity in the ventilation occurring in a patient's lungs can be assembled and by which information about that characteristic can be presented to an attending clinician in a form that is highly useful for diagnosis and treatment.

The foregoing is accomplished by the method steps outlined in claim 1 to make the presentation shown in Fig. 4 of the application. Using an inert gas wash in/wash out technique comprising steps (a) through (f) and (h), the subject's lung volume is determined for a series of breaths. Using the lung volumes so determined and the volume of gas breathed by the patient, a gas exchange efficiency is determined for the series of breaths in steps (g) and (h).

The data so obtained is then presented (step j), as exemplarily shown in Fig. 4, for data points comprising the breaths. The determined lung volume is shown on one axis, the abscissa, and the determined gas exchange efficiency on another axis, the ordinate.

The clinician sees the information so presented, as follows. As noted in paragraphs [0034], [0035], and [0036] of the present application, the volumetric portion of the lungs having the better gas exchange efficiency appear or are "found" first. In the example shown in Fig. 4, as the volume of the lung begins to appear during inert gas wash in/wash out, starting at about 1500 ml and increasing from there, the normalized data graph 23 indicates that about 2100 ml of lung volume have reasonably good gas exchange

efficiency, i.e. a relative value of 0.7 or better. The remaining, and finally determined, 500 ml of the lung exhibit markedly less gas exchange efficiency, with the finally determined portions, appearing at a lung volume of 2600 ml, having a relative gas exchange efficiency of only about 0.2 or less. A clinician is thus able to easily determine the degree of gas exchange homogeneity existing in the patient's lungs.

The claimed method described above for determining and relating gas exchange efficiencies and lung volumes and ascertaining lung homogeneity stands in distinct contrast to the disclosure of the inventor's earlier '506 patent.

The '506 Patent

The method of the '506 patent is directed to determining the functional residual capacity (FRC) of the lung. The functional residual capacity is the amount of air remaining in the lungs at the end of an ordinary exhalation. In using the method of this patent, a multi-dimension regression analysis is carried out using data sets of breathing gas volume data and inert gas concentrations to obtain the functional residual capacity. See steps 212, 214, and 218 shown in Fig. 3b of the patent.

Lack of Anticipation

The claimed method differs from that disclosed in the '506 patent in at least the following respects. First, the presently claimed method is one for determining the ventilation homogeneity of volumetric portions of the lungs. The '506 patent is directed to determining a completely different physiological aspect, functional residual capacity, the amount of air in the lung after an expiration. Second, the foregoing differences in purpose are reflected in differences in the steps of the claimed method over those of the reference. The steps of the claimed method are those necessary to determine a relationship, as shown in Fig. 4. The steps of the method of the '506 patent are directed to determining a quantity, i.e. functional residual capacity, for example in liters. The steps of the present method illustrate the inhomogeneity of the lung by a particular presentation of data as set out in claim 1, step (j) and claim 4 not employed in the '506 patent. Conversely, the steps of the present method

Appln. No. 10/650,114
Amendment dated May 13, 2005
Reply to Office Action of December 13, 2004

do not involve the first or second regression coefficients, FRC and K, respectively, described in the '506 patent.

Information Disclosure Statement

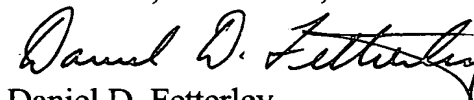
An Information Disclosure Statement, along with the appropriate certification under 35 U.S.C. §1.97(e) was filed in the USPTO on January 24, 2005. Acknowledgement and consideration of the references contained in that Information Disclosure Statement in subsequent USPTO correspondence is respectfully requested.

Conclusion

The subject matter sought to be patented in the present application is thus neither anticipated nor rendered obvious by the inventor's earlier work set out in the '506 patent. Withdrawal of the rejection and passage of the application to allowance is respectfully requested.

Respectfully submitted,

ANDRUS, SCEALES, STARKE & SAWALL, LLP

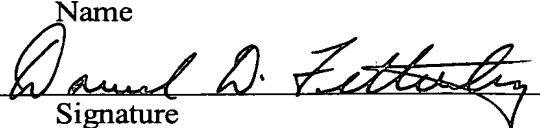


Daniel D. Fetterley
(Reg. No. 20,323)

100 East Wisconsin Avenue, Suite 1100
Milwaukee, Wisconsin 53202
(414) 271-7590

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Mail Stop - Amendment - Fee, P.O. Box 1450, Alexandria, VA 22313-1450 on the 13th day of May, 2005.

Daniel D. Fetterley	20,323
Name	Reg. No.
	5/13/05
Signature	Date